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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/717,294	09/20/96	SEED B	00786/345001

HM22/1015

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EXAMINER	
SHUMAN, J	
ART UNIT	**PAPER NUMBER**
1636	20

DATE MAILED: 10/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.	Applicant(s)
08/717,294	Seed And Haas
Examiner	**Group Art Unit**
Jon Shuman	1636

☒ Responsive to communication(s) filed on *Jul 29, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10, 17-20, and 25-28* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10, 17-19, and 25-28* is/are rejected.

☒ Claim(s) *20* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Decision on the petition before the PCT Office

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Petition to correct Inventorship in application 08/324,243 has been granted.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-10, 17-19 and 25-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Seed et al. (World Patent Application No. 96/09378).

Seed discloses synthetic genes encoding mammalian proteins that are expressed at a higher level than native genes. The synthetic genes have non-preferred codons replaced by preferred codons. Proteins such as Factor VIII may have their expression level increased by replacing codons such that expression levels can increase significantly. From 10%-90% of the codons in the natural protein are non-preferred and/or are replaced. Vectors containing the synthetic gene and mammalian cells harboring the vector are also disclosed (Seed, page 1, line 20 through page 4, line 26). Seed also teaches that in a preferred embodiment the CG sequence is highly under represented (Seed, page 17, lines 27-39 and page 25, line 22 through page 26, line 34). Seed discloses each and every aspect of the instant invention, thereby anticipating Applicants' claimed invention.

Applicants argue, in the response filed 18 November 1998 that since Dr. Seed is an inventor on the WO document and an inventor on the instant application, applicant's own work published less than 1 year prior to the filing date of the application cannot be used against him.

This is not persuasive since the inventive entity on the WO document is different from the inventive entity in the instant application and therefore the WO document represents a reference by another published within 1 year prior to applicant's filing date and is appropriate under 102(a). Please see the attached copy of PCT rule 92 bis regarding the timely filing of demands to change certain indications on PCT documents. This rejection will be maintained until the pending petition to change inventorship on the PCT document has been finalized. Please see the attached paper regarding a decision on this issue pending before the PCT Office.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4, 6-10, 18 and 28 are rejected under the judicially created doctrine of double patenting over claims 1-4, 6-9, 11, 15 and 17 of U. S. Patent No. 5,786,464 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In the instant case, Seed et. al. claim a synthetic gene encoding a protein normally expressed in an eukaryotic cell wherein at least one non-preferred or less-preferred codon in a natural gene encoding said protein has been replaced by a preferred codon encoding the same amino acid, wherein expression of said gene is at a level that is 110%, 150%, 200%, or 500% of that expressed by said natural gene in an *in vitro* mammalian cell culture system under identical conditions. Further, the synthetic gene is claimed where at least 10% or 50% of the codons in said natural gene are non-preferred, and wherein at least 50 or 90% of the non-preferred and less preferred codons have been replaced by preferred codons. The synthetic gene is claimed wherein said protein is expressed by a mammalian cell and a method is claimed for preparing said synthetic gene, comprising identifying non-preferred and less-preferred codons and replacing one or more of them with a preferred codon encoding the same amino acids as the replaced codon.

U.S. Patent 5,786,464 claims a synthetic gene encoding a protein normally expressed in mammalian cells wherein at least one non-preferred or less-preferred codon in the natural gene encoding said protein has been replaced by a preferred codon encoding the same amino acid (in claim 1), wherein the synthetic gene permits expression of said protein in a mammalian host cell at a level which is at least 110 (in claim 1), 150 (claim 2), 200% (claim 3), or 500% (claim 4) of that expressed by said natural gene in an *in vitro* mammalian cell culture system under identical conditions. The synthetic gene is claimed wherein at least 10% (claim 6) or 50% (claim 7) of the codons in said natural gene are non-preferred codons, and wherein at least 50 % (claim 8) or 90 % (claim 9) of the non-preferred and less-preferred codons have been replaced. A method is claimed, comprising identifying non-preferred and less-preferred codons in the natural gene encoding said protein and replacing one or more of said non-preferred and less-preferred codons with a preferred codon encoding the same amino acid as the replaced codon.

The overlapping subject matter is the optimization of codon usage in order to effect more efficient translation, wherein stalling is less likely to occur, and thus more protein is translated. The subject matter is overlapping in all the claims as indicated above.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Allowable Subject Matter

4. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Shuman whose telephone number is (703) 306-5819. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon Shuman

7 October 1999

DAVID GUZO
PRIMARY EXAMINER